IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF MISSOURI
WESTERN DIVISION

DONALD K. ALEXANDER	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 18-00498-CV-W-HFS
COCHLEAR AMERICAS	)	
	)	
	)	
Defendant.	)	

ORDER

Presently pending before the court are pro se plaintiff's motions for jury trial (Doc. 3), for court ruling (Doc. 4), for leave to file amended complaint (Doc. 12), to certify class (Doc. 16), and for default judgment (Doc. 18). Also pending is a motion to dismiss filed by defendant, Cochlear Americas (Doc. 7).[1] For the reasons noted below defendant's motion will be granted.

[1] As a named defendant, Cochlear Americas, waived service of summons and counsel advised plaintiff that, as a subsidiary, it was not authorized to accept service for named defendant, Cochlear Limited, an Australian entity with its principal place of business in New Wales South, Australia. (Defendant's Opp. To Mot. For Service).

Fed.R.Civ.P. 4e and Missouri Rules of Civil Procedure 54.09, 54.13, and 54.14 only allow service upon a foreign corporation by delivering a copy of the summons and petition to an officer, partner, or managing or general agent, or by delivering copies to its registered agent or to any other agent authorized by appointment or required by law to receive service of process. Dunakey v. American Honda Motor Co., Inc., 124 F.R.D. 638, 639

In his initial complaint, plaintiff alleged that he was surgically implanted with a Cochlear Americas cochlear device at the Midwest Ear Institute in Kansas City, Missouri on December 30, 2015. (Complaint: ¶ 6). He claims actual damages for personal billing in the amount of $85,000 for the implant and accessories including surgical, nursing and hospital medical expenses, and additional billing for post-surgery programming sessions. (Id). He also seeks compensatory damages in the amount of $750,000.

Plaintiff states that he has suffered permanent numbness of his left ear rim and sound wave distortion, and intends to have the implant surgically removed; followed by surgery to implant a competitive device which may subject him to, among other things, additional pain and suffering. (Id: ¶¶ 6-7).

Plaintiff has asserted claims in Count One, for false advertising and consumer fraud in violation of the Missouri Merchandising Practices Act, R.S.Mo. § 407.020(1)(3); and in Count Two claims for breach of implied warranty of fitness for a particular purpose in violation of R.S.Mo. § 400.2-315 and the Uniform Commercial Code section 2-314. (Id: ¶ 10).

(E.D.Mo. 1989). Standing alone, a parent/subsidiary relationship is not enough to render a parent subject to the court's jurisdiction. Id; citing, Volkswagenwerk Aktiengesellschaft v. Schlunk, 486 U.S. 694 (1988).

Plaintiff has not shown that Cochlear Limited is licensed to do business in Missouri or has a registered agent of its own to accept service of summons. Thus, the motion (Doc. 4) for an order ruling that service on Cochlear Limited was accomplished by service on Cochlear Americas is DENIED.

Defendant has moved to dismiss each of plaintiff's claims due to failure to state a claim upon which relief can be granted pursuant to Fed.R.Civ.P. 12(b)(6) because the claims are preempted by the Federal Food, Drug, and Cosmetic Act, (FDCA), 21 U.S.C. § 301 et seq.

Standard of Review

To avoid dismissal of claims asserted in a complaint, the complaint must include enough facts to state a claim to relief that is plausible on its face. In re Medtronic, Inc. Sprint Fidelis Leads Products Liability, 592 F.Supp.2d 1147, 1154-55 (D.Minn. 2009); citing, Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007). A plaintiff must plead sufficient facts to provide the grounds of his entitlement to relief which requires more than labels and conclusions, and for which a formulaic recitation of the elements of a cause of action will not do. Sprint Fidelis, at 1155. A complaint cannot simply leave open the possibility that a plaintiff might later establish some set of undisclosed facts to support recovery; rather, the facts set forth in the complaint must be sufficient to nudge the claims across the line from conceivable to plausible. Id.

When reviewing a motion to dismiss, the complaint must be liberally construed, assuming the facts alleged therein as true and drawing all reasonable

inferences from those facts in the plaintiff's favor. Id. A complaint should not be dismissed simply because a court is doubtful that the plaintiff will be able to prove all of the factual allegations contained therein. Id. Thus, a well-pleaded complaint will survive a motion to dismiss even if it appears that a recovery is very remote and unlikely. Id.

Discussion

Plaintiff contends that his claims of false advertising, consumer fraud, and breach of implied warranty of fitness for a particular purpose are asserted under Missouri law. He raises the claims "in connection with a sound distorting cochlear implant known …" to defendant to be incapable of transmitting undistorted sound waves accompanied by extremely common high and medium high frequency sound waves. (Complaint: ¶ 1). Plaintiff states that the sound distortion is inherent in the design and manufacturing technology used by defendant and defendant hid this information from plaintiff prior to implantation of the device. (Id).

Defendant contends that plaintiff's claims are preempted by federal law, specifically the Medical Device Amendments (MDA) to the FDCA, pursuant to 21

U.S.C. § 360k(a), and should be dismissed due to failure to allege sufficient facts upon which relief can be granted, pursuant to Fed.R.Civ.P. 12(b)(6).

Statutory and Regulatory Framework

Every medical device intended for human use is placed into one of three categories by the Food and Drug Administration (FDA), based on the risks of injury or illness the device presents, and each category is subjected to a different level of FDA scrutiny, pursuant to 21 U.S.C. § 360c(a)(1). Riegel v. Medtronic, Inc., 552 U.S. 312, 315-19 (2008); see also, In re Medtronic, 592 F.Supp.2d at 1149. Devices that either support or sustain human life or present a potential unreasonable risk of illness or injury are categorized as Class III devices under 21 U.S.C. § 360c(a)(1)(c)(ii), and are subject to the greatest level of FDA scrutiny and must complete a thorough review process with the FDA before they may be marketed. In re Medtronic, at 1149-50. Through this process, known as pre-market approval (PMA), a device maker must provide the FDA with reasonable assurance that its device is both safe and effective. Id, at 1150; citing, 21 U.S.C. § 360e(d)(2). As an implant, the cochlear implant has been classified as a Class III device. 21 C.F.R. § 860.93(a)(b); see also, Sadler v. Advanced Bionics, Inc., 929 F.Supp.2d 670, 674 (W.D.Ky. 2013).

In response to a bevy of state laws regulating medical devices largely enacted due to the failure of the Dalkon Shield contraceptive in the 1970's, Congress passed the Medical Device Amendments (MDA) to the FDCA in 1976. In re Medtronic, at 1150. The MDA include an *express* preemption clause that swept back some state obligations and imposed a regime of detailed federal oversight. Id. It restricts states from establishing requirements that relate to a device's safety or effectiveness that differs from, or adds to, any MDA requirement already applicable to the device. Id; citing, 21 U.S.C. § 360k(a). The FDA has interpreted § 360k(a) as preempting any state requirement, whether established by statute, ordinance, regulation, or court decision. Martello v. Ciba Vision Corp., 42 F.3d 1167, 1168 (8th Cir. 1994). Thus, the MDA's preemptive effect extends to state tort actions. Id.

In order to determine whether plaintiff's claims are *expressly* exempted, the Supreme Court set forth two factors to consider. Williams v. Bayer Corp., 541 S.W.3d 594, 602 (Mo. Ct. App. W.D. 2017); citing, Riegel v. Medtronic, 552 U.S. at 322-23. First, we must look to see if the FDA established requirements applicable to the cochlear implant. Id. As noted above, the implant is classified as a Class III device requiring the highest level of scrutiny under the MDA; thus, stringent requirements have been established, satisfying the first step of the preemption

analysis. The second step requires a determination as to whether the claims would impose requirements "different from, or in addition to," the federal requirements. A finding that statements made in a device's labeling are misleading in violation of state law after the FDA found the statements were not misleading when it approved the labeling would, without a doubt, be imposing requirements "different from, or in addition to" those set forth by the FDA. Williams, at 603.

Plaintiff contends that his claims of false advertising, consumer fraud, and breach of implied warranty of fitness for a particular purpose are asserted under Missouri law. He raises the claims "in connection with a sound distorting cochlear implant known …" to defendant to be incapable of transmitting undistorted sound waves accompanied by extremely common high and medium high frequency sound waves. (Complaint: ¶ 1). Plaintiff states that the sound distortion is inherent in the design and manufacturing technology used by defendant and defendant hid this information from plaintiff prior to implantation of the device. (Id). Plaintiff also states that defendant failed to caution potential recipients of the implant of the sound distortion in its marketing brochures and websites. (Id: ¶ 5). In asserting a violation of the MMPA, plaintiff claims that

defendant knowingly, intentionally, and willfully concealed the sound distortion problem before it surgically implanted the cochlear implant. (Id: ¶ 9).

Plaintiff's product liability claims of failure to warn, breach of warranty, and false advertising unquestionably relate to the safety or effectiveness of the cochlear implant, and are therefore preempted by 21 U.S.C. § 360(k)(a). In re Medtronic, 592 F.Supp.2d at 1156; affirmed in, In re Medtronic, Inc. Sprint Fidelis Leads Products Liability, 623 F.3d 1200, 1205 (8th Cir. 2010); see also, Sadler v. Advanced Bionics, Inc., 929 F.Supp.2d 670, 682 (W.D.Ky. 2017) (§ 360k(a) preempts fraud claims regarding a surgical cochlear implant based on statements that were approved or required by the FDA) . As to plaintiff's claim that defendant failed to include a warning regarding sound distortion on its label and website, it is noted that as part of the premarket approval process, the FDA examined the implant's proposed labeling to ensure it was neither false nor misleading. Thus, plaintiff's MMPA claim would impose requirements different from or in addition to the federal requirements regarding this device, and is, therefore, statutorily preempted. Williams v. Bayer, 541 S.W.3d 594, 602-03 (Mo. 2017).

Although plaintiff's claims are preempted under § 360k(a), the statute does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations because in such a case, the state duties would be

considered *parallel*, rather than *adding to* the federal requirements. In re Medtronic, at 1204; citing, Riegel, 552 U.S., at 330. However, plaintiff expressly states that his "complaint **does not** make any factual allegations whatsoever concerning FDA specifications or regulations or any factual allegation involving FDA oversight of medical devices or any conceivable form of product liability claim." (Plaintiff's Opp. Sugg.: Doc. 12, pg. 1, ¶ 1). Without such a comparison there can be no intelligible assertion of permissible parallel claims by plaintiff. Thus, an undeveloped contention cannot save this case from preemption. Riegel, supra, at 330.

Finally, a careful review of plaintiff's allegations in the proposed Amended Complaint reveals a mirror image of those claims initially asserted. In fact, plaintiff repeats that he is not asserting claims based on any type of product liability, federal statutes or case law, FDA oversight, or fraud upon the FDA, but rather, that his claims are based on Missouri consumer fraud and false advertising. Consequently, as amended, the allegations do not cure the preemption issues related to his claims, and leave to file this pleading will not be granted. Williams v. Bayer Corp., 541 S.W.3d, at 614.[2]

[2] Notwithstanding plaintiff's pro se status in this matter, defendant states, and plaintiff does not dispute, that he has received a law degree in Missouri but did not sit for the bar examination. (Defendant's Supporting Suggestions: pg. 3, n. 4). Defendant further states that plaintiff has an extensive history of pro se litigation in this courthouse.

Accordingly, it is hereby

ORDERED that defendant's motion to dismiss (Doc. 7) is GRANTED. It is further

ORDERED that plaintiff's motions for demand for jury trial (Doc. 3), court ruling (Doc. 4), leave to file amended complaint (Doc. 12), to certify class (Doc. 16), and for default judgment (Doc. 18) are DENIED as moot.

/s/ Howard F. Sachs

HOWARD F. SACHS
UNITED STATES DISTRICT JUDGE

October 11, 2018

Kansas City, Missouri

(Id). As such, plaintiff should be aware of the federal rules requiring leave of court *prior to* filing an amended pleading after an answer has been filed.